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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,784	03/06/2002	Wayne M. Barnes	60019630-0038	9712

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,784	BARNES ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *8-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

DETAILED ACTION

1. Applicants' response to the office action filed on May 20, 2005 has been entered.

Status

2. Claims 1-7 are pending. Claims 8-13 are withdrawn as being non-elected group. All arguments have been fully considered and thoroughly reviewed, and are deemed persuasive for the reasons that follow. This action is made FINAL necessitated by amendment.

New Grounds of Rejections necessitated by Amendment

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note: MPEP 2112.01 states "Products of identical chemical composition can not have mutually exclusive properties."A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658(Fed. Cir. 1990).

Thus in the following rejections the phrase "wherein combining the source of magnesium ions and the source of phosphate ions in accordance with the instructions supplied in the kit forms a precipitate at a temperature below 34^0 C" is considered as a inherent property of the kit comprising a source of magnesium ions and a source of phosphate ions and instructions for use of the kit.

Claim 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (USPN. 6,071,745).

Lin et al. teach a kit comprising one or more materials for amplifying a target nucleic acid comprising lyophilized cells, buffers, primers, probes, enzymes and other components for amplifying a target nucleic acid and instructions for using the kit (see col. 11, line 28-41), wherein the buffers comprise a source of phosphate ions and a source of magnesium ions (see col. 7, line 44-49). With regard to the claim 3, Lin et al. also teach that the kit comprises enzymes and said enzyme comprises a DNA polymerase enzyme (see col. 11, line 22-41). Accordingly the instant claims are anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al. (USPN. 5,411,876) in view of Stanley (USPN.6,207,385).

Bloch et al. teach a kit for amplifying a target nucleic acid (hot-start PCR using wax carrier) comprising

(a) a container (tube) comprising reagents for PCR in a suitable buffer, wherein said buffer comprises a source of inorganic salt ions (see col. 22, line 37-44, line 50-53, indicating that the inorganic ion as KCl); and a container (tube) comprising a source of magnesium ions

($MgCl_2$) Wherein said instructions comprise mixing of the components of the two containers (see col. 22, line 45-62);

(b) instructions for using the components in the two containers (see col. 22, line 46-47).

With regard to claim 2, Bloch et al. teach that said source of Magnesium ion is magnesium chloride (see col. 22, line 45);

With regard to claims 3, Bloch et al. also teach that the kit comprises a DNA polymerase and other PCR reagents such as primers, deoxyribonucleotide triphosphates (dNTPS) (see col. 22, line 40-44). However, Bloch et al. did not teach specifically that the inorganic ions as phosphate ions and the source is phosphoric acid and precipitate formation at temperature below 34^0 C.

Stanley teaches a method using a polymeric carrier comprising PCR reagents and amplification of a target nucleic acid, wherein, Stanley teaches that the method comprises a source of phosphate ions, and use of such ions in promoting precipitation (salting-out) of certain types of high molecular weight species such as proteins in the aqueous solution and thereby enhancing the attachment of molecular species (oligonucleotides) to the water-soluble intermediate reagent (nucleic acid target) (see col. 7, line 25-43).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the kit comprising source of inorganic ions and a source of magnesium ions as disclosed by Bloch et al. in a manner of as taught by Stanley with the inclusion of phosphate ions for the purpose of increasing the salting-out process which helps in isolating DNA from other cellular components and enhances the specific amplification of the target nucleic acid. One skilled in the art would be motivated to combine the kit as disclosed by

Bloch et al. in a manner taught by Stanley because Stanley explicitly taught the use of a source of phosphate ions, and use of such ions in promoting precipitation (salting-out) of certain types of high molecular weight species (at temperatures ranging from 20-25^0 C), such as proteins in the aqueous solution and thereby enhancing the attachment of molecular species (oligonucleotides) to the water-soluble intermediate reagent (nucleic acid target) (see col. 7, line 18-43). An ordinary artisan would have a reasonable expectation of success that inclusion of a source of phosphate ions would result in enhancing the amplification process by salting-out the unnecessary cellular components away from the target nucleic acid as taught by Stanley and such modification of the kit would be obvious over the cited prior art in the absence of secondary considerations.

B. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloch et al. (USPN. 5,411,876) in view of Stanley (USPN.6,207,385) as applied to claims 1-3 above, and further in view of Barnes et al. (USPN. 6,214,557).

Bloch et al. in view of Stanley teach a kit for amplifying a target nucleic acid as discussed above in 4A.

However, neither Bloch et al. nor Stanley specifically teach DNA polymerase as KLENTAQ1, Pfu, DEEP VENT or Tth.

Barnes et al. teach compositions or formulations comprising thermostable DNA polymerases that include KLENTAQ1 (Klentaq-278), Pfu, Deep Vent DNA polymerases (See col. 8, line 45-67, col. 9, line 1-15). Barnes et al. also teach that the thermostable DNA polymerases exhibit substantially reduced activity at room temperatures, but exhibit substantially similar polymerase activity at optimum temperatures at about 68^0 C. (see col. 8, line 45-65).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the kit for amplifying a target nucleic acid comprising source of phosphate ions and a source of magnesium ions as disclosed by Bloch et al. in view of Stanley with the inclusion of a thermostable DNA polymerase for the purpose of increasing the target amplification of the target nucleic acid. One skilled in the art would be motivated to combine the kit as disclosed by Bloch et al. in view of Stanley with the inclusion of athermostable DNA polymerase as taught by Barnes et la. because Barnes et al. explicitly taught the thermostable DNA polymerases exhibit substantially reduced activity at room temperatures, but exhibit substantially similar polymerase activity at optimum temperatures at about 68^0 C. (see col. 8, line 45-65). An ordinary artisan would have a reasonable expectation of success that inclusion of the a thermostable DNA polymerase would result in enhancing the amplification process by exhibiting minimal activity at room temperature and enhanced activity at optimum temperatures as taught by Barnes et al. which is more appropriate to use in hot-start PCR reactions as taught by Bloch in view of Stanley and such modification of the kit would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

5. With regard to the rejection made in the previous office action under 35 USC 101, Applicants' arguments and the amendment are fully considered and the rejection is withdrawn herein in view of the amendment.

6. With regard to the rejection made in the previous office action under 35 USC 102(e), Applicants' arguments and the amendment are fully considered and the rejection is withdrawn herein in view of the amendment and new grounds of rejections.

7. With regard to the rejections made in the previous office action under 35 USC 103, Applicants' arguments and the amendment are fully considered and the rejections are withdrawn herein in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the

organization where this application or proceeding is assigned are 571-273-8300 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
Examiner, Art Unit 1637

JEFFREY FREDMAN
PRIMARY EXAMINER